Chapter 11

PHARMACY

11.1. Purpose. The primary purpose of the pharmacy is to provide quality pharmaceutical services that comply with all appropriate medico-legal requirements along with cost effective drug and medical supply management services. Pharmaceutical services will be in compliance with all appropriate federal rules and regulations guiding the practice of pharmacy. The approved drug formulary is provided as Appendix D.

11.2. Staffing. The pharmacy department at the DIHS medical facilities shall be directed by a pharmacist (Chief Pharmacist) who shall be appropriately licensed and who shall report to the HSA. The HSA will provide general guidance for the operation of the pharmacy service within the framework of the medical facility and the regulations and standards of the DIHS. Technical and administrative supervision will be provided as necessary by the Pharmacy Consultant, DIHS and/or the Chief, Field Operations.

11.2.1. Non-Professional Pharmacy Personnel (technicians, aids, etc.). Non-professional pharmacy personnel work directly under the supervision of a pharmacist such that the chief pharmacy officer is fully aware of all of the technician's activities involving the handling of medications. All assigned duties of the technician shall be consistent with their training and experience.

11.2.2. Coverage During Absence of Pharmacist.

- If the pharmacist will be gone for a week or longer, the HSA will either obtain the services of a contract pharmacist or will arrange the Telepharmacist coverage.
- For periods of time less than one week, a pharmacy technician or properly trained and oriented RN, NP or PA may be assigned to prepare prescriptions for dispensing. A physician or dentist will subsequently check the prescriptions for accuracy and sign-off on the dispensing in the medical record before medication is delivered to patient.

11.2.3. Orientation of Pharmacy Personnel. The purpose of an orientation is to develop an understanding of the purpose, function, responsibilities of the department; and its relationship to other DIHS departments, services and personnel.

The method will be as follows:

- Introduction to existing department staff
- Explanation of job description and duties
- Explanation of expected levels of job performance
- Completion of orientation to pharmacy areas explained

11.3. Regulations and Standards. The Chief Pharmacist will be responsible for the purchase, the inventory control, and the record keeping of all Drug Enforcement Administration (DEA) controlled substances and DIHS

restricted items. The pharmacy service will comply with all appropriate PHS, DIHS, DEA and other federal regulations, NCCHC standards, and all appropriate national standards of practice.

DIHS pharmacists are responsible for insuring compliance of the above policies and are encouraged to maintain a copy of national guidelines promulgated by the American Society of Health System Pharmacists. These guidelines are a means of assuring comparability with national, private sector, and pharmacy practice standards. Additionally, each medical facility should be on the mailing list for the Food and Drug Administration (FDA) informational bulletins relating to adverse drug reactions and drug recalls.

11.3.1. DEA Registration. The DIHS pharmacist is responsible for securing and maintaining a current DEA Registration Number. In the absence of a pharmacist, the Clinical Director will perform this duty.

11.3.2. State Licensure. Since the DIHS is a joint venture of two federal agencies (INS and PHS), the DIHS pharmacies will neither obtain nor maintain state pharmacy licenses. Questions related to state pharmacy licensure requirements shall be referred to the DIHS Pharmacy Consultant for either explanation and/or assistance in resolution.

11.3.3. Pharmaceutical Company Representatives. Entry into a medical facility by pharmaceutical company representatives shall require INS OIC approval. Such approval shall be obtained by the pharmacist through the HSA. Pharmaceutical representatives shall be limited to non-patient care areas and shall be excluded from all detainee areas for safety and security reasons. Pharmaceutical samples can only be left with the pharmacy and their use limited by drug formulary policy. Non-formulary sample products must be approved for use by the Pharmacy and Therapeutics Committee in the same manner as those products being requested for addition to the formulary. All sample products will be controlled and dispensed by the pharmacy.

11.4. Pharmacy and Therapeutics (P&T) Committee. The National P&T Committee shall be responsible to serve in an advisory capacity to the Executive Council, in all areas related to drug and medical supply management. The P&T Committee's primary functions shall be to assure quality and cost effective support of clinical and administrative services as well as compliance with appropriate standards. This includes, but is not limited to:

- Developing and maintaining a national formulary of pharmaceutical and medical supplies
- Evaluating clinical data, literature and field input for the purpose of formulary modification
- Reviewing and re-evaluating the list of items available on emergency carts, first aid kits, and toxicology kits
- Reviewing all drug experience and drug defect reports
- Monitoring and reviewing the use of approved drugs for non-approved uses
- Providing recommendations after consultation regarding appropriate personnel, equipment and space for effective and efficient pharmacy and medical supply
- Reviewing and approving, in conjunction with other DIHS Consultant, extender prescribing privileges

11.4.1. Committee Membership: The Chairperson may bring in specialty consultants as needed for committee membership. Otherwise, DIHS P&T Committee shall consist of the following voting members:

- Physician, Chairperson
- Pharmacist, Secretary
- Nurse, Member
- NP/PA, Member
- Administrator, Member

11.4.2. Meetings. Members shall meet annually and supplementally, when necessary, via conference telephone calls. Items for agenda consideration should be submitted to the Secretary at least two weeks prior to each meeting. The Secretary shall discuss recommendations and follow-up requirements with the Chairperson and prepare and disseminate an agenda at least 5 days prior to each scheduled meeting.

11.4.3. Minutes. A permanent record (minutes and other documentation) of proceedings and activities will be kept on file with the Secretary. Copies of the minutes will be circulated in a timely manner to the members of the Committee and the Local Governing Body. The HSAs will disseminate them to all clinical staff on-site.

11.5. Drug Formulary. Each medical facility shall use the DIHS national drug formulary. The formulary is a listing of all of the pharmaceuticals approved for routine use by the clinical staff of the DIHS. No drugs except those listed in the formulary shall be routinely purchased or supplied.

11.5.1. Inventory. Smaller facilities may elect not to stock all of the available drugs as a result of practice or storage limitations. It is recommended that each medical facility stock at least one drug in each of the available drug classes in order to provide a viable therapeutic alternative and to minimize costs and problems related to the writing and acquisition of contract prescriptions.

11.5.2. Non-Formulary Requests. Authorization for use of items not in the formulary should be requested from the senior staff physician through the pharmacist. A Request for Non-Formulary Medication (Form IHS-177) must be completely filled out by a prescriber for each non-formulary drug prescribed. After approval by the senior staff physician, it shall be forwarded to the pharmacist. These forms will then be sent to the DIHS Medical Director or the Pharmacy Consultant as required.
Non formulary medications that are locally initiated require approval by the Chief, Clinical Services. Non-formulary medications that detainees were stabilized on prior to arrival at SPCs do not require this approval, but a copy of the request must be forwarded to the Pharmacy Consultant.

11.5.3. Drug and Medical Supply Sources. The Veterans Administration Prime Vendor Program is the mandatory first source for all Pharmacy and Medical Supplies. If Prime Vendor is unable to supply the needed item(s) in the time frame required, other possible sources include the PHS Service Supply Service Center at Perry Point, Maryland, Defense Depots and Military Installations, or private vendors with Federal Supply Schedule Contracts. When a required item is not available from any of these sources or when there is an emergency requirement for a specific item, the pharmacist may utilize a local pharmacy or other

wholesaler. Such local purchases, however, should be limited as costs are significantly higher than for the same item from a federal source.

11.5.4. Storage and Inspections. Drugs shall be stored separately by the type of drug category in addition to temperature, flammability and security requirements and manufacturers recommendations. When storage space permits, drugs will be stored in alphabetical order, by generic name, within each of the following categories:

- Oral - Inhalant
- Oral - Internal
- External - Topical
- Injectable
- Ophthalmic
- Otic
- Nasal - Inhalant
- Narcotics and Controlled Substances
- Abusable Supplies
- Flammable Items
- Thermolabile Items

11.5.4.1. Inspection. The pharmacist, or trained designee, shall physically inspect all drug storage areas on a monthly basis to assure the absence of expired, recalled or deteriorated drugs, the proper condition of stored drugs, and compliance with manufacturer's storage recommendations.

11.5.4.1.1. Checklist. The pharmacist shall develop a standardized inspection checklist to be used to document the monthly inspections. Completed copies will be maintained in the pharmacy files. The pharmacist shall assure that problems or deficiencies identified during the monthly inspections are documented and corrected when possible. Items beyond the realm of the pharmacist will be referred to the HSA for correction.

11.5.4.2. Surplus/Expired Drugs. The pharmacist shall designate and clearly mark a specific secure area within the medical facility for the storage of surplus or expired drugs pending appropriate disposal. The pharmacist shall dispose of surplus/expired drugs as necessary in accordance with the HHS Material Management Manual. If the surplus/expired drug is a narcotic or controlled substance, it will be disposed of according to instructions from the DEA.

11.5.4.3. Temperature Monitoring - All medications will be maintained inside a temperature range indicated by their manufacturer as being appropriate for long-term storage. Room temperatures will be maintained between 59 degrees F and 80 degrees F. Medications labeled as "Keep Refrigerated" will be maintained between 34 degrees F and 46 degrees F. A daily check will be made to assure the room and refrigerator temperatures are within limits. The temperatures will be logged on the "Daily Refrigerator & Room Temperature Log". Food products will not be stored in refrigerators designated for medication storage.

11.6. In-Service Education. Pharmacists will provide in-service education to DIHS staff on appropriate pharmacy, drug, or medical supply management topics as funds and time are available to support these activities. The pharmacist shall maintain a file with the following information for all in-services provided:

- In-Service Date(s) and Time(s)
- Title and Outline of Presentation or Copy of Handout
- Sign-In List of Audience Present
- Name and Title of Presenter(s)

11.7. Reports and Forms. The following reports shall be prepared and sent through the HSA to the Chief, Field Operations and the Pharmacy Consultant:

11.7.1. Quarterly Narrative Report. The pharmacist shall submit a Quarterly Narrative Report of Activities, by the 10th day of each of the following months: October, January, April and July. The report should include accomplishments, problems and measures taken for resolution, meetings attended and facilities visited.

11.7.2. Workload Statistics. Workload statistics will be submitted on a monthly basis, and should include:

- Outpatient prescriptions
- Clinic/supply issues
- Drugs issued for dispensing according to RN protocols
- Night nursing cabinet issues
- 24-hour cart filling units
- Unit dose pre-packs
- Multiple dose pre-packs

11.7.3. Other Reports. The pharmacist shall complete a Medwatch Report (FDA Form 3500) after each reportable adverse event or product problem and a Medical Device and Laboratory Product Problem Reporting Form FDA-2519F after each reported product problem.

The pharmacist shall forward the completed original to the FDA with copies to the pharmacy files (not all problems meet the reporting requirements, instructions on the forms should be reviewed prior to filing these reports).

11.7.4. Forms. Standardized forms shall be used within the pharmacy service. These forms may be ordered at http://propshop.psc.gov. The pharmacist shall assure availability of the following PHS and General Services Administration Standard Forms:

- IHS-17-2 Prescription Blank
- IHS-174 Monthly Report for Narcotics and Other Controlled Substances

- HRS-176 Perpetual Inventory of Narcotics and Other Controlled Substances Pharmacy)
- IHS-248 Pharmacy Requisition
- HRS-251 Drug Sensitivity Label
- IHS-335 Pharmacy Chronological Control Log

11.8. Prescribing Medication. The following disciplines are authorized to prescribe medications for detainees at DIHS medical facilities:

- Physicians
- NP/PA (Under approved guidelines, a copy of which is maintained in the pharmacy)
- Registered Nurses (Under approved guidelines, a copy of which is maintained in the pharmacy)

Any prescription written for a narcotic or controlled substance by a NP/PA shall be cosigned by the supervising physician prior to dispensing.

Contract providers empowered to prescribe medications by their state licensing agencies are authorized to prescribe medications for detainees referred to them for care. The DIHS pharmacist will orient the contract providers to the formulary system and provide the contractor with a copy. The pharmacist will maintain an up-to-date file for each authorized provider, to include typed or printed full name, title, legal signature, social security number, and DEA number.

11.8.1. Writing Prescriptions. All in-house prescriptions shall be written under the plan section of the SOAP format on either the Chronological Record of Medical Care (Standard Form 600) or other approved sheet. Additionally, prescriptions to be filled by contract pharmacies and prescriptions for narcotics and controlled substances shall be written on a separate prescription blank (IHS 17-2). All prescriptions to be filled at a contract pharmacy shall authorize generic substitution unless pre-approved for a specific brand name product by the senior staff physician. All prescriptions shall be prescribed by their generic name. Brand name products require a completed and approved Request for Non-Formulary Medication Form (IHS-177). No drug abbreviations shall be used.

Each prescription shall include the following information:

- Date of order
- Detainee's name and Alien Number
- Drug name, dosage form, strength and quantity
- Directions for use
- Refill information, when appropriate
- Provider's stamped name, title and legal signature
- DEA or PHS social security number when a narcotic or controlled substance

11.8.2. Verbal Prescription Orders. Verbal prescription orders shall be limited to after-hours or emergency situations. Verbal prescription orders may be communicated by an authorized provider to the pharmacist. Verbal orders for an emergency prescription, except for Schedule II narcotics, may also be

communicated to a registered nurse or NP/PA, but must be cosigned within 72 hours by the responsible provider. All verbal orders for medication must be reduced to writing in the detainee health record as soon as possible after receipt by the provider receiving the verbal order.

Verbal orders for Schedule II drugs may only be accepted by the pharmacist in accordance with all applicable DEA requirements. These prescriptions will immediately be reduced to writing on a prescription blank and cosigned as described above. If Schedule II narcotics are necessary for emergency use, then cosignature must occur within 24 hours or by the end of the next business day.

11.8.3. Automatic Stop Orders. Medical facilities shall comply with automatic stop orders for DEA controlled substances, psychotropic drugs, and other prescribed medications for which patient compliance should be monitored. Automatic stop orders shall be enforced whenever a prescriber does not specifically define the duration of drug therapy. A new prescription is required upon expiration of the listed time limits. No maintenance drugs for chronic conditions, however, shall be discontinued without prescriber concurrence. Medications shall not be put on hold.

Enforcement procedures for automatic stop orders shall be determined and implemented at the local level.

The following automatic stop orders apply:

SHORT-STAY UNIT PATIENTS

Therapeutic Category	Automatic Stop Order (time)
Large Volume Parenterals	48 Hours
Narcotics and Controlled Substances	96 Hours
Antibiotics	96 Hours
Anticoagulants	96 Hours
Steroids	96 Hours
All Other Drugs	7 Days

AMBULATORY PATIENTS

Therapeutic Category	Automatic Stop Order (time)
Narcotics/Controlled Substances	14 Days
Psychotropics	14 Days
Antibiotics	14 Days
Steroids	10 Days
Initial Chronic Medications	14 Days
Maintenance Chronic Medications	14 Days

These limits apply only when the provider does not specify a length of therapy or number of doses to be dispensed. The maximum number of days therapy that a provider may order for a detainee is described in Medical Policy. Current INS policy places a two week limit on the amount of medication that may be given to the detainee at one time. The pharmacy will refill the prescription in two week supplies to cover the period of therapy requested by the provider.

11.9. Ambulatory Care Prescription Filling. All prescriptions will be dispensed and administered in accordance with the following:

- Ambulatory care patient prescriptions must be filled by either a pharmacist, physician, or designee working under the direct supervision of an physician.

- The pharmacist or designee shall review each prescription request and the health record prior to its filling. All questions that arise with respect to each outpatient prescription shall be resolved with the responsible provider prior to dispensing the prescription.

- The pharmacist or designee shall enter the following information adjacent to each prescription prior to dispensing the medication:

  - Prescription number
  - Any clarifying information
  - Stamped name/signature and title

- All ambulatory care patient prescriptions prepared in the absence of a pharmacist shall be reviewed by the physician or dentist prior to dispensing. Those prescriptions for narcotics and/or controlled substances or prescriptions that will accompany the detainee upon discharge MUST be dispensed by a physician in the absence of a pharmacist.

- All prescriptions dispensed shall be issued an individual pharmacy control number. The prescription number will be stamped next to the prescription in the health record. Prescription numbers will be generated through the computer or through the use of Bates stamps.

- The pharmacist shall assure that all medications are properly labeled so as to conform with federal regulations. In addition to the medical facility name, address, and pharmacy phone numbers, prescription labels shall contain at least the following information:
  - Prescription number
  - Date of prescription
  - Detainee name and Alien Number
  - Drug name, strength and quantity
  - Directions for use
  - Prescriber name and title
  - Pharmacist's name or initials
  - DEA Cautionary Labels if a narcotic or controlled substance and auxiliary labels

- Prepackaged items for after hours ambulatory use shall be labeled with the necessary auxiliary labels and with a label containing the name, strength, quantity, and general directions for use affixed to the container. The practitioner dispensing the medication will fill in the date, detainee name and Alien number, and prescriber name and title. The affixed label should be able to accommodate this information.

- Intravenous medication for short-stay unit or outpatient use shall be labeled with the appropriate auxiliary labels and with a label containing the name, strength, quantity, and specific directions for use.

- The pharmacist shall assure the availability of prescription, auxiliary and prepackaging labels.

- DIHS staff will enter all relevant drug sensitivity information (ie. Penicillin allergy, etc.) under the drug sensitivity section of the Medication Profile Form (DIHS-840) in large, print bold.

- All detainees will be positively identified prior to their receiving medications from pharmacy staff.

- No medications will be dispensed to detainees in glass containers (except Nitroglycerin). Medications purchased in glass stock containers will be transferred to approved plastic prescription containers.

11.9.1. Compounding. All compounded medications will be considered non-formulary items. A non-formulary request form must be approved prior to compounding. The pharmacist will either compound the required prescription or refer it to a contract pharmacy. The pharmacist shall assure that adequate records and controls are maintained for each compounded item. All compounded item labels shall carry an appropriate expiration date based on the expiration dates of each ingredient.

11.9.2. Ambulatory Medication Profile. An Ambulatory Medication Profile shall be maintained in the health record for each detainee receiving medication. All medications dispensed by the pharmacy shall be entered on the Ambulatory Medication Profile prior to dispensing or issuance. The generic drug name, dosage form, strength, instructions for use and the quantity dispensed or issued shall be entered in the Ambulatory Medication Profile for each drug order. Each page of the Ambulatory Medication Profile will contain complete patient information on the bottom left corner.
This information may be embossed from the patient card, or a label generated by the DIHS medical records system.

11.9.3. Prepackaging. Prepackaging of pharmaceuticals shall be tailored to the medical facility requirements and standardized in operation. The pharmacist shall utilize products that are commercially available in either unit dose or unit of issue sizes when possible. All prepackaged medication labels shall contain the drug name, dosage form, strength, quantity in prepack, prepack control number, and expiration date (6 months from date prepackaged or manufacturer's expiration date if less than 6 months shelf life remains).

When the item must be prepackaged, the pharmacist shall assure that records are maintained for each prepackaged item and contain the following:

- Control number
- Date
- Drug and strength
- Manufacturer
- Manufacturer's control or lot number
- Manufacturer's expiration date

- Prepackage size
- Amount prepackaged
- Name or initials of individual doing prepacking/checking of prepacking

A seven digit control numbering system will be utilized as follows:

- The first two numbers represent the month
- The second two numbers the year
- The last three numbers represent the chronological order in which prepackaged, beginning with 300

For example, 0495303 is the third item prepackaged in April 95.

11.9.4. Patient Package Inserts (PPIs). The pharmacist will maintain a supply of PPIs for all drugs on the formulary requiring such PPIs. PPIs will be provided with each new prescription for each medication requiring such an insert and documented in the health record.

11.9.5. Medication Dispensing Incidents. Medication dispensing incidents shall be reported, documented and reviewed by the PI Committee. Medication dispensing incidents include, but are not limited to the following:

- Incorrect drug or strength issued or dispensed
- Drug container incorrectly labeled
- Medication order in health record not filled/dispensed
- Medication dispensed to the wrong detainee

Medication dispensing incidents require immediate notification of the prescriber or the physician on call. A Medical/Drug Incident Report QMD 010 will be completed for any of the above described medication dispensing incidents by the individual directly responsible for the incident. The completed form will be forwarded to the individual's immediate supervisor with a copy to the HSA. The senior staff physician will routinely review medication dispensing incidents at Performance Improvement meetings.

11.9.6. Medication Administration. The following disciplines are authorized to administer medications to detainees:

- Physicians
- Dentists
- NP/PAs
- Registered Nurses
- LPN/LVNs
- Pharmacists
- INS detention officers and contract guards, after appropriate training
- Contract providers empowered to administer medications by their state licensing agencies

11.9.6.1. Pill Line - The pharmacist shall develop and implement a distribution system for supervised

dosing of restricted medications at all medical facilities. Procedures at each medical facility shall take into consideration staffing, hours of operation, equipment and space. The following medications will be administered through this system:

- All narcotics and controlled substances.
- All psychotropic medications.
- Any other drug that the local P&T Committee determines should be restricted because it lends itself to abuse.
- Any medication for which the clinical director feels patient compliance should be monitored. See Pill Line SOP 11.9.6.1.

11.9.6.2. Distribution of OTC's by Detention Enforcement Officers (DEO) and Contract Security Officers. Tylenol (Acetaminophen) 325mg will be available in the camp for distribution by trained DEO or Contract Security Officers. A log will be kept to monitor utilization of this medication.

11.9.6.2.1. Procedure. The pharmacist or a medical provider will prepare and provide 50 unit doses of 2 tablets each for the camp along with a Tylenol Distribution Log (HSD form 60). Each officer will be trained to give two tablets for pain or fever upon a detainee's request. The officer will document in the log sheet the date, name, and amount given.

The dosage may be repeated in 3 to 4 hours and again documented in the log. If more is requested by the detainee, he/she will be instructed to complete a sick call request to be seen in the clinic. A new supply of Tylenol will only be given when a completed log sheet is submitted. The utilization of Tylenol in the camp will be monitored for appropriateness of distribution and documentation by the pharmacist or medical provider through the Performance Improvement Committee.

11.9.7. Telepharmacy/Mail Order Pharmacy Services. In selected facilities where prescription volume is not sufficient to justify the services of an on-site pharmacist or where the position of pharmacist cannot be filled, pharmacy services may be provided via a mail order pharmacy contractor or a telepharmacy system. Under the telepharmacy system, a DIHS staff pharmacist at a remote site will receive orders from local providers, review them, and input them into the telepharmacy computer system. This system will then send a signal to a computer controlled dispensing unit at the local facility which will issue a label and pre-packaged container of medication. Since the facilities using these programs are each unique, specifics on these operations will be set forth in local operating procedures at each facility.

11.10. Narcotics and Controlled Substances. Medical facilities shall comply with all appropriate DEA and PHS regulations and policies relating to the control, accountability, and security of narcotics and controlled substances.

The pharmacist is responsible for the receipt, storage, security, dispensing, and maintenance of appropriate records for all narcotics and controlled substances (including alcohol and spirituous liquors) and abusable supplies procured by or transferred to the medical facility pharmacy. The Chief Nurse is responsible for the storage, security, administration, and maintenance of appropriate records for all narcotics and controlled substances

(including alcohol and spirituous liquors) and abusable supplies issued to the Nursing Service. In the absence of a Chief Nurse, the HSA will designate another health care provider to assume these responsibilities.

11.10.1. Routine Inventories. A perpetual inventory control system shall be maintained for all narcotics and controlled substances and for all abusable supplies (ie. syringes, needles, prescription blanks, etc.) stored in the pharmacy. The pharmacist will conduct a physical inventory of all narcotics and controlled substances assigned to the pharmacy at least once monthly, preferably on the last working day of each month. A copy of the monthly inventory report (IHS-174) will be maintained with the controlled substance records. The Pharmacy Consultant will audit narcotics and controlled substances records during periodic site visits.

11.10.2. Biennial Inventory. The pharmacist will conduct a biennial inventory of all narcotics and controlled substances in accordance with DEA regulations and using the following criteria. The inventory shall be maintained by the pharmacist and filed with the controlled substances records.

- Inventory includes all narcotics and controlled substances in the pharmacy and throughout the medical facility.
- Inventory is conducted either at the beginning or end of the workday on May 1st of each odd numbered year.
- Inventory is recorded on either an approved DEA form or a locally generated form that includes the drug name, dosage form, strength, and quantity of each narcotic or controlled substance. The list is followed by the name, address and telephone number of the pharmacy, date and time of the inventory, and the printed name, title, and legal signature of the pharmacist conducting the inventory.

11.10.3. Transfer of Custody. Changes involving personnel having custody of narcotics and controlled substances require a written transfer of such custody. Whenever possible, a joint inventory by the departing and arriving custodians will be taken, utilizing a Transfer of Custody of Narcotics and Spirituous Liquors Form (HSA-245).

Whenever a joint inventory is not possible, the physician designated by the HSA shall temporarily accept custody until arrival of the replacing custodian. The physician will assure compliance with transfer of custody requirements in the absence of the assigned pharmacist.

11.10.4. Prescriptions for Narcotics and Controlled Substances. A prescription order for a narcotic or controlled substance may be issued only by a physician, dentist, or other registered practitioner who is:

- Authorized to prescribe narcotics and controlled substances by the jurisdiction in which licensed to practice their profession
- Registered under the Controlled Substances Act or exempt from such registration (i.e. military and PHS Physicians)

When narcotics and controlled substances are prescribed by a NP/PA, such prescriptions shall be cosigned by an authorized physician prior to dispensing or administration. During the hours that a pharmacy is closed or in the absence of the pharmacist, narcotics and controlled substances may be dispensed only by the

physician or through a contract pharmacy. Nurses may administer a narcotic or controlled substance upon orders of a physician for a short-stay unit patient or as a one-time dose.

A prescription order for a controlled substance may be given verbally or by telephone by a staff physician and accepted by the mid-level practitioner, but this order must then be cosigned by the ordering physician within 24 hours or the close of the next clinic working day.

11.10.5. Record Keeping. Medication orders for DEA controlled substances will be signed/cosigned by a physician/dentist, and will be accompanied by a properly completed Prescription Blank Form (HRSA 17-2).

The pharmacist shall develop specific record keeping procedures for narcotics and controlled substances that comply with DEA, DIHS and medical facility requirements and that include, but are not limited to requisitions, receipts, individual prescriptions, issuance to other medical facilities, and use in bulk compounding. Discrepancies in count involving narcotics and controlled substances should be documented by the DIHS staff person discovering the discrepancy.

In cases of recurring shortages or loss of a significant quantity of narcotics or controlled substances, a complete investigation and written report shall be made to the Chief, Clinical Services, through the HSA, with a copy to the Pharmacy Consultant. The appropriate DEA Office shall be notified of any theft or significant loss of a narcotic and controlled substance. DEA Form 106 (obtainable from DEA) will be completed and forwarded to that office, with appropriate copies to the pharmacy file, HSA, and the Pharmacy Consultant.

11.11. Security. Pharmacies and drug storage areas shall be secured at all times and access shall be limited to approved DIHS staff. The HSA will work with local INS administration to assure that each pharmacy and drug storage area have adequate locking devices. The pharmacist will assure that all narcotics and controlled substances are stored in either a safe or a locked cabinet within the locked pharmacy or drug storage area.

11.11.1. Emergency Medications/Supplies. Emergency drugs and medical supplies shall be stored in a locked cabinet accessible only to the person in charge. An inventory control system shall be maintained for the contents of the emergency/night cabinet.

11.11.2. Non-DIHS Staff. Contract pharmacists should have access to the pharmacy in order to assure continuity of care in the absence of the pharmacist. Non-medical personnel (e.g. custodians or contract workers) must be accompanied by DIHS staff at all times when in the pharmacy or drug storage areas.

11.11.3. Detainee Workers. Detainees will not be allowed access to the pharmacy or to drug storage areas except for housekeeping purposes. In those instances, detainees must be directly supervised by INS staff at all times.

11.11.4. Key Control. Only designated DIHS staff shall normally have direct access to the pharmacy in the form of keys or knowledge of the door lock combination. This includes the pharmacist, the pharmacy technicians, and the physician.

11.12. Drug Recall System. The DIHS, in accordance with the FDA has established a drug recall system. All drugs that are recalled by the manufacturer or the FDA will be removed from use and handled according to the instructions in the recall. The pharmacist at each SPC is responsible for recording lot numbers at the time pharmaceuticals are checked in. On receipt of drug recall from depots, manufacturers, or from the FDA Enforcement Reports, the pharmacy will immediately determine if the recall pertains to pharmaceuticals in stock by checking lot numbers against those involved in the recall. All medications involved in the recall will then be collected from all locations in the clinic. All recalled products obtained should be separated from normal operating stocks and marked "QUARANTINED-DO NOT USE" until they are picked up and returned to the manufacturer.

In the case that the product recall is of substantive clinical significance, all active detainees who may have received the medication should be notified of the recall and evaluated for complications resulting from the administration of the drug. A written log should be kept of all recalls, including the action taken and the results.

11.13. Patient Medication Counseling. Detainees will receive counseling pertinent to the medication they are receiving at the time of dispensation, which includes the following:

- Directions for use, including frequency of administration
- Significant side effects
- Purpose or pharmacological action of the medication
- Potential interactions with other medications or food
- Any other information that may be relevant

The counseling may be given by verbal instruction, written materials, or a combination of both. Medication counseling materials are available in both English and Spanish for most medication contained in the formulary. Some materials are available in other languages, such as Haitian, Creole, Chinese, etc. SPC Pharmacists can contact the DIHS Pharmacy Consultant regarding the availability of these materials. SPC Pharmacists are encouraged to have translations of medication counseling made in the languages of the detainees of that facility, if translation services are available. Copies of translations should be forwarded to the DIHS Pharmacy Consultant, so that they can be shared with other facilities.

If written counseling materials are not available in the language the detainee speaks, the pharmacist should take advantage of English-based materials that have pictograms indicating times of day, food, bed-time, etc. If language barriers severely limit communication, with the detainee's consent, another detainee may be used to translate the information. However, the accuracy and the quality of the translation may vary.

11.14. Biomedical Safety Certification. All electrical equipment located in the pharmacy must be checked and certified by a Biomedical Equipment Technician.

11.15. Backing of Pharmacy Program Data. Data will be backed up onto a removable disk system (CD-RW) once a week.

An "off-site" disk backup will be performed weekly and this data disk will be stored in a secured area away from the pharmacy.

11.16. Incoming Detainees Medications. All medications brought into DIHS detention facilities by detainees must be turned over to the medical provider during medical screening. The provider will examine the medications, document them in the detainee record, and determine if they are still necessary and appropriate for the detainee. The medications will then be placed into the detainee's property (provided detainee does not have access to them) and medication stocked by the clinic pharmacy issued if there is still a valid need for this particular therapy. If detainee arrives at a time when the pharmacy is closed, and the provider feels the detainee requires the medication, the medication should be placed on the "pill line" and administered on a dose-by-dose basis until the pharmacist can process the new prescription.
If the medication is not stocked by the clinic pharmacy and if the provider feels that a comparable substitute is not available, the detainee's medication may be used. If additional medication is needed, the Non-Formulary Medication Request Form (IHS-177) will be filled out and forwarded to the Pharmacy Consultant. Only medications that are properly labeled and bear clear markings on the tablet/capsule to indicate legitimate manufacturer will be used. Detainees will be allowed to keep inhalers and nitroglycerin that are in their possession.

11.17. Possession of Medications by Detainees. Detainees may only possess medications that were ordered by or reviewed and approved by DIHS providers. Medications that may not be possessed by detainees at any time include controlled drugs and psychotropic agents. A detainee may only possess one container of a particular medication at any given time and prescription medications must be labeled with the detainee's name. If a detainee is found in possession of more than one container of a particular medication or prescription medication that is not labeled with their name, it will be considered contraband and be grounds for possible disciplinary action by INS officials. Detainees will be allowed to possess only reasonable quantities of over-the-counter (OTC) medications. A reasonable quantity is defined as a 3 day supply. Detainees will only be allowed to possess a 14-day supply or a single unit (inhalers, eye drops, etc.) of any prescription medication. Quantities in excess of these amounts will be turned back into the clinic for appropriate disposition.

11.18. Drug Utilization Evaluations. Drug Utilization Evaluation is a mandatory function at all DIHS facilities. The CD is responsible for assuring this function is carried out. If there is a pharmacist assigned to the facility, they will conduct the studies. If the facility has no pharmacist on staff or if the position is temporarily vacant, the CD will perform the studies or delegate the task to another staff member. Lack of a staff pharmacist will not be grounds to ignore this requirement.

The functions may be broken down and shared with staff as follows:

- Identification of areas to study and development of criteria should be a collaborative effort between the CD, HSA (cost is one of the factors in developing criteria), and providers assigned. This can be reviewed and approved at the staff and PI meetings.

- Identification of charts falling into the criteria. This can be done via the mail order billing summaries or computer searches, depending upon the system used at the facility.
- Pulling of charts would be the responsibility of the records department.
- Final review of the charts against the established criteria would be done by the CD or another designated provider.

Ultimately, the responsibility belongs to the Clinical Director, but this distribution of subordinate tasks can reduces his/her workload.